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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/196,673	11/20/1998	JOHN MCCAFFERTY	28111/32106B	9420

7590 03/04/2004

IP PROSECUTION
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WASHINGTON, DC 20004-2402

EXAMINER	
PONNALURI, PADMASHRI	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/196,673	MCCAFFERTY ET AL.	
	Examiner	Art Unit	
	Padmashri Ponnaluri	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *45-145* is/are pending in the application.

4a) Of the above claim(s) *66-77 and 110-144* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-65,78-109 and 145* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 March 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 07/971,857.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/22/03 has been entered.

Status of Claims

2. Claims 1-43 have been canceled, and new claims 44-144 have been added by the amendment filed on 11/20/98. New claim 145 has been added and Claim 44 has been canceled by the amendment filed on 10/10/00.

3. Claims 45-145 are currently pending in this application.

4. Claims 66-77, 110-144 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6, filed on 1/21/00.

5. Claims 45-65, 78-109 and 145 are currently being examined in this application.

6. The indicated allowability of claims 45-65 and 145 is withdrawn in view of the newly discovered reference(s) to Ladner et al.

Information Disclosure Statement

7. The petition to expunge according to 37 CFR. 1.59 (b) filed on 9/11/02 has been noted and placed in the application.

8. The decision on the petition to expunge is held in abeyance until the application is allowed or an Ex parte Quayle action, or a Notice of Abandonment is mailed, at which time the petition will be decided.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 46, 48-65, 78-109 and 145 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0436597 B1 (Ladner et al).

Ladner et al teaches a method of obtaining a nucleic acid encoding a proteinaceous binding domain (refers to instant claim specific binding domain) that binds a predetermined target material (e.g., see page 5, Summary of the invention). The reference teaches a population of variegated genetic packages (refers to instant claim library), each said genetic package being genetically altered and having an outer surface protein (OSP) (refers to instant claim capsid protein or coat protein), and a nucleic acid construct coding a chimeric potential binding protein

and outer surface (refers to the fusion protein of the instant claims) and expression of the construct results in the display of said chimeric potential binding protein. The reference teaches that the genetic packages are contacted with the predetermined target material (refers to instant claim contacting the library of filamentous bacteriophage particles with a desired ligand of the instant claims), and recovering at least one genetic package displaying the chimeric binding protein which bound to the target, and amplifying the selected genetic package (displaying the binding protein) in vivo or in vitro. The reference teaches that once the binding protein is identified or selected, it can be used many times as the starting point r developing different novel proteins that bind to the target (refers to instant claims derivative specific binding pair) (e.g., see page 9).

The reference teaches displaying initial potential binding domain (IPBD) on outer surface of filamentous phages (e.g., see page 18). The reference teaches that the preferred OSP for use when genetic package is M13 is gene III protein (refers to gene III capsid protein of the instant claims) (e.g., see page 19, line 34).

The reference teaches that the choice of IPBD, and the T4 lysozyme is one among them (e.g., see page 20). The reference teaches that the T4 lysozyme is 164 residues long (refers to instant claim limitation 'enzyme is at least 100 amino acids') (e.g., see page 20, line 39). The reference further teaches that the target material may for example be selected from a non-macromolecular organic compounds, in which case the IPBDs may comprise more than about 80 amino acid residues. The reference teaches that the chosen IPBD is a T4 lysozyme (enzyme) (e.g., see page 21). The reference clearly anticipates the claimed invention.

11. Claims 46, 48-65, 78-109 and 145 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,223,409 (LADNER et al).

Ladner et al teach a method of obtaining a nucleic acid encoding a binding protein having proteinaceous binding domain (refers to instant claim specific binding pair) that binds a predetermined target material comprising: a) preparing a variegated population of amplifiable genetic packages (refers to the library of filamentous bacteriophage particles of the instant claims) and each genetic package has a chimeric protein construct comprising DNA encoding a potential binding domain, which is not a single chain antibody, and outer surface signal for display of potential binding domain; b) causing the expression of chimeric potential binding proteins and display of the potential binding domain on the outer surface of said packages; c) contacting said genetic packages with a predetermined target material; d) separating the genetic packages displaying on its outer surface potential binding domain that binds to the target material; e) recovering at least one package displaying on its outer surface a chimeric binding protein comprising a successful binding domain which bound to the target, and amplifying the binding domain in vivo or in vitro (e.g., see claim 1).

Ladner et al teach that the method of obtaining nucleic acid encoding a binding protein further comprises, I) isolating from the nucleic acid construct of genetic package bearing a successful binding domain (SBD), a nucleic acid fragment consisting essentially of DNA encoding said SBD to deduce the amino acid sequence of SBD and then preparing a second nucleic acid construct comprising DNA encoding a SBD (e.g., see claim 7). The reference teaches that the potential binding domain is selected from the group consisting of a) a binding domain of bovine pancreatic trypsin inhibitor, protease inhibitors or lysozymes (refers to the

enzyme or fragment thereof the instant claims) (see e.g., claim 11). The reference teaches that a second binding protein is prepared using the first SBD and recombinant technology (e.g., see claim 29). The reference claim 39 teaches that the replicable genetic packages are filamentous phage (refers to the instant claim bacteriophage vectors). The reference further teaches that the outer surface transport signal is provided by the gene III protein of the filamentous phage (e.g., see claim 41). The reference teaches that IPBD is T4 lysozyme of 164 residues (e.g., see column 21, line 13)(refers to the instant claim enzyme of at least 100 amino acids). The reference further teaches that if the target is a small molecule , the IPBD is a protein of 80-200 residues (see e.g., column 22) (refers to the enzyme which is at least 200 amino acids of the instant claims), such as ribonuclease (104 residues), egg white lysozyme (104 residues), T4 lysozyme (164 residues) (e.g., see column 22) . Thus the reference clearly anticipates the claimed invention.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 45-65, 78-109 and 145 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Ladner et al (US Patent 5,223,409) or EP 0436597 B1 (LADNER).

[NOTE the rejection makes reference to the US Patent 5,223,409 disclosure since the disclosure of the both references is same and both the references claim priority to the same US Patent application 07/240,160, and assignee of the both references is Protein Engineering Corp.]

Ladner et al teach a method of obtaining a nucleic acid encoding a binding protein having proteinaceous binding domain (refers to instant claim specific binding pair) that binds a predetermined target material comprising: a) preparing a variegated population of amplifiable genetic packages (refers to the library of filamentous bacteriophage particles of the instant claims) and each genetic package has a chimeric protein construct comprising DNA encoding a potential binding domain, which is not a single chain antibody, and outer surface signal for display of potential binding domain; b) causing the expression of chimeric potential binding proteins and display of the potential binding domain on the outer surface of said packages; c) contacting said genetic packages with a predetermined target material; d) separating the genetic packages displaying on its outer surface potential binding domain that binds to the target material; e) recovering at least one package displaying on its outer surface a chimeric binding protein comprising a successful binding domain which bound to the target, and amplifying the binding domain in vivo or in vitro (e.g., see claim 1).

Ladner et al teach that the method of obtaining nucleic acid encoding a binding protein further comprises, I) isolating from the nucleic acid construct of genetic package bearing a

successful binding domain (SBD), a nucleic acid fragment consisting essentially of DNA encoding said SBD to deduce the amino acid sequence of SBD and then preparing a second nucleic acid construct comprising DNA encoding a SBD (e.g., see claim 7). The reference teaches that the potential binding domain is selected from the group consisting of a) a binding domain of bovine pancreatic trypsin inhibitor, protease inhibitors or lysozymes (refers to the enzyme or fragment thereof the instant claims) (see e.g., claim 11). The reference teaches that a second binding protein is prepared using the first SBD and recombinant technology (e.g., see claim 29). The reference claim 39 teaches that the replicable genetic packages are filamentous phage (refers to the instant claim bacteriophage vectors). The reference further teaches that the outer surface transport signal is provided by the gene III protein of the filamentous phage (e.g., see claim 41). The reference teaches that IPBD is T4 lysozyme of 164 residues (e.g., see column 21, line 13)(refers to the instant claim enzyme of at least 100 amino acids). The reference further teaches that if the target is a small molecule , the IPBD is a protein of 80-200 residues (see e.g., column 22) (refers to the enzyme which is at least 200 amino acids of the instant claims), such as ribonuclease (104 residues), egg white lysozyme (104 residues), T4 lysozyme (164 residues) (e.g., see column 22) .

The reference does not teach that the enzyme (IPBD) is at least of 200 amino acids. Ladner et al teach the method of identifying nucleic acid encoding an enzyme (potential binding domain) from plurality of genetic packages displaying chimeric protein comprising the enzyme and a gene III coat protein. The reference teaches that the potential binding domain is T4 lysozyme of 164 residues (e.g., see column 21, line 13). The reference has not taught a potential binding domain of at least 200 amino acids. However, the reference teaches that depending on

the size of the target the potential binding domain size is determined, and if the target is a small molecule , the potential binding domain is a protein of 80-200 residues (see e.g., column 22). Thus it would have been obvious to one skilled in the art at the time the invention was made to use an enzyme or fragment of the size at least 200 amino acids. A person skilled in the art would have been motivated to use the methods taught by Ladner et al to obtain new or modified nucleic acids encoding enzymes of at least 200 amino acids, because Ladner et al teaches all the required criteria in selecting the potential binding domains and use the selected binding domains (enzymes) having desired affinity to the target in designing a family of potential new enzymes.

Conclusion

15. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner is on Flex Schedule and can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

Pp
01 March 2004

PADMASHRI PONNALURI
PRIMARY EXAMINER